510(k) Summary

SUBMITTER:	GUNZE LIMITED, Medical Division 46 Natsumegaichi, Aono, Ayabe, Kyoto 623-8513 JAPAN Tel: +81 773 42 8035 Fax: +81 773 42 8593
CONTACT PERSON:	Noriyuki Morikawa Regulatory Affairs
DATE PREPARED:	November 15, 2013
TRADE/PROPRIETARY NAME:	NEOVEIL™ Tube/Sheet Type Suture and Staple Line Reinforcement Material
COMMON/USUAL NAME:	Staple line reinforcement material
CLASSIFICATION NAME:	Mesh, Surgical, Polymeric
REGULATION:	21 CFR 878.3300
PRODUCT CODE:	OXC
PREDICATE DEVICE(S):	Gore SEAMGUARD Bioabsorbable Staple Line Reinforcement (K043056), PARIETEX™ Composite Ventral Patch (K120506), SYMBOTEX™ Composite Mesh (K131969) PERI-STRIPS DRY Staple Line Reinforcement (K040415)
DEVICE DESCRIPTION:	As packaged, NEOVEIL™ is a suture- and staple-reinforcement product composed of 100% bioabsorbable polyglycolic acid (PGA). This nonwoven product is dyed with D&C Green No.6 in order to make it readily visible to the surgeon. Two forms of NEOVEIL™ are provided. The Tube type model constitutes of pre-formed porous bio-absorbable nonwoven sheets and is intended for staple-line reinforcement. The Tube type model is provided in the form of sleeves, one for the cartridge and one for the anvil on a corresponding stapler. After deployment of the tube type reinforcement material, the non-degradable elastic knits, comprised of polyurethane and nylon, are removed and discarded along with the PGA tacking sutures. The Sheet type model is simply a porous

fibrous bio-absorbable sheet which is intended for suture-line reinforcement. The thickness of the bioabsorbable NEOVEIL™ staple line reinforcement ranges from 0.1 mm to 0.85 mm.

Mesh weave characteristics and pore size are not applicable since NEOVEIL™ is nonwoven material. Average basis weight of the NEOVEIL model ranges from 35 to 225 (g/m^2).

INTENDED USE:

NEOVEIL™ is indicated for use in surgical procedures in which soft tissue transection or resection with suture or staple line reinforcement is needed. NEOVEIL™ can be used for reinforcement of suture or staple lines during lung resection, liver resection, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, and small bowel procedures.

SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICES:

NEOVEIL™ bioabsorbable suture and staple line reinforcement is substantially equivalent to the predicate device, SEAMGUARD bioabsorbable staple line reinforcement (K043056) in terms of design for the following technological characteristics:

- Nonwoven polyester surgical meshes
- Thickness
- Mesh density
- Tensile strength
- Suture pullout strength
- Tear resistance

The only difference, however, is that the subject device is polyglycolide whereas the SEAMGUARD predicate device is polyglycolide-trimethylene carbonate. Both are neither electrically powered nor use software to function. Both are mechanically manipulated by the surgeon under direct visual control (for open surgery) or endoscopic control (for endoscopic usage) in placement and use.

The subject device is also equivalent to the predicate device, PERI-STRIPS DRY Staple Line Reinforcement (K040415), for stiffness and is equivalent to the predicate devices, PARIETEX™ Composite Ventral Patch (K120506) and SYMBOTEX™ Composite Mesh (K131969), for the green dye.

MATERIALS:

All materials of NEOVEIL™ have been evaluated in accordance with ISO 10993-1 and are acceptable.

PERFORMANCE DATA:

Testing has been performed in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh, including the tests shown in the list below which support the determination of substantial equivalence of NEOVEIL™ to the predicate device.

The list below provides the tests performed in vitro:

a. Thickness
b. Mass
c. Density
d. Tensile strength: Bench
e. Degradation: In vitro tensile strength loss 1 week and 2 weeks
f. Suture pull out strength
g. Tear strength
h. Insertion/Removal Forces
i. Firing Force
j. Staple Formation
k. Staple Line Stiffness
l. Buttress Material Stiffness

The list below provides the tests performed in vivo:

a. Free Bleed Evaluation
b. Air Leak Test
c. Burst Evaluation
d. Staple Formation
e. Resorption

CONCLUSION OF SUBSTANTIAL EQUIVALENCE:

The device described in this submission is substantially equivalent to the predicate device due to the provided data and information to support the similarities between the two devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 15, 2013

GUNZE LIMITED
Nobuya Onishi
46 Natsumegaichi, Aono
Ayabe, Kyoto 623-8513
Japan

Re: K130997
Trade/Device Name: NEOVEIL™ Tube/Sheet Type Suture and Staple Line Reinforcement Material
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXC
Dated: October 18, 2013
Received: October 25, 2013

Dear Mr. Onishi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jiyoung Dang -S

On behalf of
Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (If known): K130997

Device Name : **NEOVEIL™ Tube Type staple line reinforcement material**

and

NEOVEIL™ Sheet Type suture line reinforcement material

Indications For Use:

NEOVEIL™ is indicated for use in surgical procedures in which soft tissue transection or resection with staple or suture line reinforcement is needed. NEOVEIL™ can be used for reinforcement of suture or staple lines during lung resection, liver resection, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, and small bowel procedures.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130997